Remarks

Claims 1-3 are pending in this application. Claims 4 through 10 have been added. These new claims represent claims that were canceled in copending application No. 10/108,237 and added to the present pending application. No new matter has been added as a result of the presently added claims.

Double Patenting

(I) Claims 1-3 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 29-33 of copending Application No. 10/108,237. Applicants respectfully disagree.

Pursuant to 37 CFR 1.321(c), Applicants agree to file a terminal disclaimer in order to obviate the double patenting rejection.

Rejection of claims 1-3 are rejected under 35 U.S.C. 112, first paragraph

Claims 1-3 are rejected under 35 USC 112, first paragraph because the specification, while being enabling for methods and formulations comprising galactomannan and either 5-FU or adriamycin, does not reasonably provide enablement for methods and formulations comprising galactomannan and any chemotherapeutic agent. Applicants respectfully disagree.

The Examiner contends that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims without undue experimentation.

The presently claimed invention is directed toward the use of galactomannan in combination with a chemotherapeutic agent, thereby reducing the toxicity of the chemotherapeutic agent. The teaching of the present application is consistent with this assertion. The Examiner contends that only 5-FU and adriamycin in combination with galactomannan are taught in the present application. This contention is not supported by

the text. For example, pages 10ff teach the use of several chemotherapeutic agents with galactomannan. Beginning in the second paragraph, various chemotherapeutics are disclosed and considered to be within the scope of the presently claimed invention. These pharmaceuticals are well known in the art and their characteristics, including indications, are well appreciated by practitioners.

Adriamycin and 5-FU were employed simply as examples and should not be construed as exhausting the possible drug combinations with galactomannan. The use of these drugs demonstrated the utility of combining a chemotherapeutic agent with galactomannan and should not be interpreted as being limiting. A skilled artisan will appreciate that if these drugs demonstrated efficacy with galactomannan, then other chemotherapeutics will most likely benefit from the presence of galactomannan.

Galactomannan is a simple polymeric structure comprising a mannose backbone with galactose residues stemming from the backbone. The Examiner suggests that it is difficult to predict whether other chemotherapeutics (other than 5-FU and adriamycin) will interact with the galactomannan in such a manner as to be ineffective. A review of the structure of galactomannan reveals that the likelihood of such an interaction is highly improbable. The galactomannan serves as a vehicle for the drug. There is no evidence supporting the contention that there is a specific interaction between galactomannan and a chemotherapeutic agent leading to the pharmacological benefit of such a combination. Moreover, there is no evidence presented in the specification or in the art that would suggest that galactomannan would molecularly interact with a chemotherapeutic agent in such a manner as to render it (or the combination) ineffective. This suggestion is complete speculation without sufficient foundation by the Examiner.

The demonstrated efficacy of adriamycin and 5-FU is sufficient to demonstrate the utility of chemotherapeutic agents. In so far as the Examiner contends that undue experimentations is implicated in the use of other chemotherapeutic agents with galactomannan, this is simply not the case. All a practitioner need do is to prepare a composition according to the teachings of the application and follow what is taught in the

present application. There is no undue experimentation involved in employing other chemotherapeutic agents.

As far as predictability is concerned, one would predict the behavior of other chemotherapeutic agents would act in a similar manner as the two agents tested - there is no reason to think otherwise. Other chemotherapeutic agents should act in a consistent manner as they are classified in this class of pharmaceuticals, i.e., as chemotherapeutic agents. These drugs often have specific indications and can be used in combination with galactomannan without departing from their indications.

In summary, the present specification provides enabling teaching to one of ordinary skill in the art as to how to practice the presently claimed invention. Therefore, Applicants respectfully request reconsideration and withdrawal of the present rejection.

Rejection of claims 1-3 are rejected under 35 U.S.C. 112, second paragraph

Claims 1-3 are rejected under 35 USC 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant respectfully disagrees.

The Examiner states that it is unclear as to what the "effective doses" of the active agents in the composition are intended to accomplish. The Examiner queries: "Do applicants intend the dose to have reduced toxicity, to be a chemotherapeutic, or to be some combination of the components?"

The "effective dose" of the chemotherapeutic agent reagent refers to that amount of chemotherapeutic agent necessary to illicit a therapeutic benefit. The reduced toxicity phenomenon is associated with the presence of galactomannan. Each pharmaceutical has associated with it a dose-response curve which is sigmoidal. Typically the inflexion point provides the favorable therapeutic index. Movement to the right of the curve (higher dosages) provides for a more toxic profile. Galactomannan appears to shift the curve such that toxicity normally associated with a particular dose is attenuated.

In conclusion, in view of the above amendments and remarks, Applicants respectfully request the Examiner find the pending claims allowable and issue a Notice of Allowance.

Enclosed please find a check in the amount of $55 to cover the required fee for the Terminal Disclaimer under 37 CFR 1.20(d). Please charge any underpayment of fees to or credit any overpayment of fees to Deposit Account No. 03-2410.

The Examiner is invited to call the undersigned attorney at (617) 854-4237 should he determine that a telephonic interview would expedite prosecution of this case.

Respectfully submitted,

Stephen J. Gaudet, Ph.D.
Attorney for Applicants
Reg. No. 48,921

Date: 1/4/05